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10/783,438	02/19/2004	Geof Auchinleck	13332.1001	7772

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EXAMINER	
TRAIL, ALLYSON NEEL	
ART UNIT	PAPER NUMBER
2876	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,438	AUCHINLECK, GEOF	
	Examiner	Art Unit	
	Allyson N. Trail	2876	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-14* is/are allowed.

6)☒ Claim(s) *15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment

1. Receipt is acknowledged of the Amendment filed January 28, 2005.

Claim Objections

2. Claim 1 is objected to because of the following informalities:

Re claim 1, line 11: replace "labelling" with --labeling--.

Re claim 1, line 16: replace "information" with --information;--.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al (2003/0009244) in view of Grunes et al (2004/0257231).

Engleson et al teaches the following in regards to claim 15:

"The patient wears an identification device that includes a barcode that can be read by a barcode reader connected to the bedside CPU. Medication to be administered to the patient in the course of the patient's treatment is identified with a label that is printed by a barcode printer in the pharmacy or by the manufacturer's supplied barcodes on unit dose packaging. When the medication is administered to the patient by a caregiver, the caregiver uses the barcode reader connected to the bedside

CPU to read the barcode on the patient's identification device and the barcode on the label identifying the medication to be dispensed. The patient management system compares the patient's identity with the medication and verifies that it is the correct medication for the patient. Additionally, the caregiver may also have an identification device that bears a barcode with the caregiver's name and other information. Using the barcode reader, the care giver's identity can thus be stored in the database and linked to the treatment given to the patient to ensure complete and accurate tracking of all treatment given to the patient." (Paragraph 0014).

Engleson et al fails to teach storing the blood in a refrigerated storage and labeling the blood with an RFID tag.

Grunes et al teaches the following in regards to claim 15:

"D. Storage of Evidence. Some evidence, such as blood, can degrade over time, and must be preserved under controlled conditions. Another aspect of the present invention is the use of RFID technology to tag and monitor such evidence. In that respect, evidence may be provided with an RFID tag as generally described herein, and placed in a climate-controlled environment such as a refrigerated area, a dry area, a warm area, or the like. For example, a blood sample may be contained in a bag, and the bag (and RFID tag) stored in a refrigerator having a temperature maintained at 4.4 degrees C. (40 degrees F.)." (Paragraph 0037).

In view of Grunes et al's teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply Engleson et al's method of reading the tag associated with both the medication to be administered to the patient as

well as the caregiver and including a computer for recording the administered medication and the caregiver who administered the medication for administering blood transfusions to patients. Although Engleson et al does not specifically teach every type of treatment which can be administered to the patient, it is clear that the method of reading the medication label and the caregiver's label allows for documenting which caregiver administered the medication to a certain patient. Grunes et al teaches that blood samples must be stored in a refrigerated area in order to maintain its quality. Additionally, Grunes et al teaches labeling each sample with an RFID tag for easy recognition. One would be motivated to use Engleson et al's administering method with use with administering blood transfusions in order to easily locate the caregiver who administered the transfusion and easily determine the blood type by reading the RFID tag placed on the blood sample.

5. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al (2003/0009244) in combination with Grunes et al (2004/0257231) and in further view of Fox et al (2005/0086071).

Engleson et al's teachings in combination with the teachings of Grunes et al are discussed above. The combination however fails to teach the caregiver's ID tag comprising a RFID tag.

Fox et al teaches the following in regards to claim 17:

"The caregiver identification device 12 preferably also includes the barcode identifier, RFID, or other machine-readable identifier 5." (Paragraph 0043).

In view of Fox et al's teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an RFID tag to identify the caregiver as taught by Fox et al. As discussed above, a barcode identifier, RFID, or other machine-readable identifier may be used to identify the caregiver. One would be motivated to use an RFID tag because RFID tags are capable of storing large amounts of data compared to a simple barcode. Using an RFID tag would enable detailed information regarding the caregiver to be stored and easily retrieved by reading the tag.

6. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al (2003/0009244) in combination with Grunes et al (2004/0257231) and Fox et al (2005/0086071) and in further view of Meek, JR et al (2004/0108795).

Engleson et al's teachings in combination with the teachings of Grunes et al and Fox et al are discussed above. The teachings above additionally disclose including an identification code for each medication to be administered to the patient (claim 19). The combination however fails to teach the storage means including a lock under the control of the computer.

Meek, JR et al teaches the following in regards to claim 18:

"The invention relates generally to an apparatus and method for providing access to items to be dispensed, and relates more particularly to the automatic dispensing of medical supplies." (Paragraph 0002).

"A variety of systems are used for transferring (i.e., from the storage location to the remote locations) and for dispensing (i.e., from the remote locations to the patient) the medical supplies. A system may use, for example, mobile dispensing carts which

are stocked at the centralized storage area and then wheeled to the remote location. The medical supplies may then be dispensed directly from the mobile dispensing cart for administering to the patient. Alternatively, a dispensing system may use a stationary dispensing cabinet located at the remote location. Medical supplies are dispensed from the dispensing cabinet for later administering to the patient. A restocking cart, loaded with replacement medical supplies from the centralized storage location, is used to replenish the stationary dispensing cabinet." (Paragraph 0005).

"A user is required to logon to the computer (thereby identifying who is removing medications). After identifying a patient, the user is presented with a list of medications that have been approved for administering to the identified patient (thereby addressing the problem of incorrect dispensing). Records are kept for each dispensing event thereby creating an audit trail." (Paragraph 0015).

"The automated dispensing cabinet also includes a control computer operable to lock and unlock the plurality of drawers and to control the position of the catch of each of the bins." (Paragraph 0020).

"Additionally, an aspect of the present invention relates to a method for dispensing an item contained in remote dispensing system. The method comprises granting a user access to the remote dispensing system having a plurality of lockable drawers with a plurality of lockable bins, accepting dispensing information from the user, unlocking at least one of the plurality of drawers, wherein the unlocked drawer contains an item to be dispensed." (Paragraph 0021).

In view of Meek, JR et al's teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a locking mechanism for locking the storage means of medication or blood which is to be dispensed to a patient. One would be motivated to include a locking means to ensure that the only the verified caregiver is able to access medical equipment and medications. By including a locking means, mistakes are less likely to occur.

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al (2003/0009244) in combination with Grunes et al (2004/0257231), Fox et al (2005/0086071), and Meek, JR et al (2004/0108795) and in further view of Zerhusen et al (2003/0052787).

Engleson et al's teachings in combination with the teachings of Grunes et al, Fox et al, and Meek, JR et al are discussed above. The combination however fails to teach unlocking the storage means when a request includes an identification code that matches a code in the storage means.

Zerhusen et al teaches the following in regards to claim 20:

"If, at block 68, the correct patient is identified and is due for medication 42, computer 12 receives nurse identification information as illustrated at block 72. Input device 38 scans a bar code tag associated with the nurse or automatically detects a unique identification signal from a badge or RFID tag assigned to the nurse. Computer 12 then determines whether the nurse is an authorized caregiver for administering medication 42 by comparing the signal received at block 72 to a database of authorized caregivers available from hospital network 34 as illustrated at block 74. If the nurse is

not authorized to administer medication 42, then access to medication 42 in locked medication box 46 is denied at block 70. If the nurse is authorized, then computer 12 opens locked medication box 46 and receives identification information from medication 42 as illustrated at block 76. Medication 42 is illustratively scanned using a bar code reader. In addition, computer 12 may identify medication 42 or locked medication box 46 by detecting a unique identification signal transmitted by a badge or RFID tag associated with medication 42, locked medication box 46, or other medication container." (Paragraph 0083).

In view of Zerhusen et al's teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a comparison means used in order to ensure that the storage box or bin should be unlocked. Each of the above references stresses the importance of administering the correct medication/blood to the correct patient. Using a computer comparison method would only further guarantee that this is achieved. Any extra precaution is a benefit when the patient's safety is at stake.

Allowable Subject Matter

8. Claims 1-8 are objected to above, but would be allowable if the objection were overcome.

9. Claims 9-14 are allowed over the prior art of record.

10. The following is an examiner's statement of reasons for allowance: The best prior art of record, taken alone or in combination, fails to specifically teach or fairly suggest the method for tracking blood transfusions and method for collecting and storing in a

computer database information about blood transfusions, disclosed in the current invention. Although prior art has teachings of tracking the movement of blood and further teaches the importance of administering the correct medication/blood/treatment to the correct patient by obtaining identifying information for a patient and providing the patient with a wristband, which includes patient identifying information, the prior art taken of record fails to teach each of the specific and detailed limitations of the claimed method. The claimed method for tracking blood transfusion includes collecting a blood sample from a patient and testing the sample to determine the type of blood required by the patient, allocating from a supply of blood units a blood transfusion unit for the patient, wherein the blood transfusion unit contains the type of blood required by the patient and wherein the blood transfusion is marked with an identifying code. The method further includes labeling the allocated blood transfusion with a compatibility label, wherein the label comprises the patient identifying information and the identifying code. Also included in the tracking method is the generation of a blood unit request slip for the patient, wherein the slip includes the patient identifying information, retrieving the blood transfusion unit and verifying the unit's identity by comparing the patient identifying information on the blood unit request slip to the patient information on the compatibility label on the patient allocated blood transfusion unit, comparing the patient information from the patient's wristband to the patient identifying information on the compatibility label on the patient allocated blood transfusion unit, and lastly, comparing the identifying code marked on the patient allocated blood unit with the identifying code on the compatibility label on the patient allocated blood transfusion unit. The claimed

method for collecting and storing in a computer database information about blood transfusion includes limitations not disclosed in prior art. These limitations include reading patient identification information from a wristband and printing a blood sample identification label, wherein the label includes the patient's information. This label is applied to the blood sample. The claimed method further includes transmitting patient information to a computer database each time a blood sample identification label is printed, selecting a blood unit suitable for transfusion into the patient from a supply of blood units and marking the blood unit with a unique blood unit identification code. Further still, the method includes reading the patient identification information and the blood unit identification code from the compatibility label, reading the patient identification information from the wristband, and comparing the patient information from the wristband to the patient identification information on the compatibility label. The blood unit identification code on the compatibility label is compared with the blood unit identification code on the blood unit and an alarm is provided if the patient identification information from the wristband does not match the patient identification information on the compatibility label or if the blood unit identification code on the compatibility label does not match the blood unit identification code on the blood unit, and lastly transmitting the patient identification information read from the wristband, the blood unit identification code read from the blood unit, and the patient identification information and blood unit identification read from the compatibility label to a computer database.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

11. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection. It is believed that Engleson et al in combination with various references teaches the apparatus disclosed in claims 15-20. In view of the amendments made to claims 1 and 9, claims 1-14 are indicated to be allowable over prior art (pending the correction of claim 1).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Allyson N. Trail* whose telephone number is (571) 272-2406. The examiner can normally be reached between the hours of 7:30AM to 4:00PM Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee, can be reached on (571) 272-2398. The fax phone number for this Group is (703) 872-9306.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**allyson.trail@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Allyson N. Trail
Patent Examiner
Art Unit 2876
May 9, 2005

JARED J. FUREMAN
PRIMARY EXAMINER